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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,277	08/22/2000	M. Bud Nelson	B-28	8660

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/643,277

Applicant(s)

NELSON ET AL.

Examiner

David A. Saunders, PhD

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 5/15/03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 11-17, 20-28, 31-40 and 46-62.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's response has clarified the record as to what he intends to claim by reciting "indicator". For what applicant intends, the term --indication-- would be more appropriate than "indicator" in claims 10, 20, 32 and 54. The term "indication" is conventionally used in claim language for clinical diagnostic methods, in a concluding step that relates the presence/amount of a diagnostic marker to the presence/absence/stage/course of a disease condition. The term "indicator", on the other hand, implies a chemical entity which provides a signal response in an assay. The fact that applicant used the term "indicator" as an entity to be claimed (nonelected claims 18-19, 29-30, 41-42) implied to the examiner that the term "indicator" meant some physical/chemical entity and led to confusion in examination of elected claims.

Claims 10, 20, 31, 46 and 54 remain confusing by failing to recite how the affinity ligand which does not comprise a detection reagent participates to form any sort of complex, to which the affinity ligand which comprises a detection reagent becomes bound (Nothing even recites that a complex including these two affinity ligands is formed). While applicant's urgings may be enlightening, the claims per se must clearly define the cooperative relationship of all of the recited reagents, without which there is a gap in the claimed method steps.

Regarding the terms "comparing" and "difference", the examiner concurs that these need not be interpreted in any mathematical sense.

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 / 684